

Remarks

In response to the outstanding rejections and the interview of 13 September 2007 with the Examiner and his Supervisor Johann Richter, Applicant has amended the relevant claims to specify that the bowel cleansing compositions recited contain "no additional electrolytes"; thus electrolytes, including those used in prior art PEG-ELS bowel cleansing compositions (see e.g., page 2 of the specification and cited prior art) to maintain body electrolyte balance during use, are excluded from the claimed compositions.

In the course of the interview and in the "Interview Summary" the Examiner and his Supervisor agreed that the term "no additional electrolytes" is supported by the specification, e.g., the six Examples of colonoscopy patients cleansed with a dry prep composition of PEG powder and disodium phosphate powder. It was further agreed that claims as thus amended would comply with all §112 requirements.

In the Office Action mailed 28th June, 2007, the Examiner withdraws the §112 rejections previously applied, and addresses "assertions" made by Applicant that "need to be addressed" (page 2). The Examiner contends that the claims as presented permit electrolytes such as those in clear diet powders and flavor packs to be present in the composition. The Examiner further argues that the statement in the specification that, "If the patient receives a sufficient amount of liquids containing sodium and potassium ions to satisfy hunger, no supplemental electrolytes need be used with the PEG/phosphate compositions", has not been shown to refer to the PEG/ELS (PEG/electrolyte solutions) discussed in the specification. The only other electrolytes mentioned in the specification besides those present in the liquid diets referred to are the PEG-ELS solutions which have been used in the art for decades in conjunction with PEG bowel cleansers. The Examiner cites no other plausible source of the electrolytes in the sentence at issue. It is noted that the quoted sentence is merely stating that the PEG/NaP compositions of the invention do not provide a RDA

(recommended daily allowance) of potassium and sodium electrolytes, in contrast to PEG-ELS solutions, and these must be obtained from another source, which must be in liquid form.

That said, in view of the amendments herein, the resolution of these §112 issues in the reported interview, and the fact that the Examiner has not clearly relate these allegations to a rejection or formal objection, renders the above comments on Applicant's "assertions" irrelevant to the present Office Action. The Examiner maintains the rejection of the claims under 35 USC §103, relying upon nine combined references: WO 98/43654 in view of Cleveland *et al.* (US Patent 6,048,900); DiPalma *et al.*; Wood *et al.* (US Patent 5,498,925); Vining (US Patent 5,782,762); Robb-Nicholson; Christine *et al.* (US Patent 3,330,311); Matsuoka *et al.*; and Afridi *et al.*

This rejection is based in large part on the Examiner's allegation that the claims as written do not explicitly exclude electrolytes (page 7, paragraph 3). In view of the amendments to the claims herein as discussed *supra*, it is submitted that this rejection is now moot, and withdrawal is accordingly requested.

With respect to the disclosure of the primary reference, WO 98/43654, this reference has been addressed at length throughout the extensive prosecution of this application and Applicant refers here to the comments of record on this reference. The reference does not "teach the combination" of PEG and sodium phosphates as the Examiner contends; it merely provides a list of many dozens of known laxatives and bowel cleansers, and comments that these agents can be combined in any known way in any numbers for use. The Patent Office has long recognized that such disclosures are simply attempts by applicants to preempt future innovations which do not rise to the level of "teachings" within the meaning of 35 USC §103, as they would otherwise subvert the patent system. Further, Applicant is unable to find any reference whatsoever to "electrolyts" in this reference.

Not one of the references discloses a combination of NaP/PEG without supplemental/additional (used interchangeably

herein) electrolytes. DiPalma *et al.* and Cleveland *et al.* disclose laxatives comprising only PEG, which as discussed in the specification and elsewhere, are well-known in the art and are conventionally used without added electrolytes.

As the Examiner himself describes, Afridi *et al.* report that PEG-ELS is in wide use for lavage (bowel cleansing) but about 5 to 20% of patients cannot tolerate the preparation owing to difficulty drinking the large amounts of water that must be ingested with the amount of PEG necessary for a satisfactory bowel cleansing, and/or the nausea, vomiting and/or abdominal discomfort associated with the PEG-ELS solution (due to the side effects of the electrolytes). Accordingly, the researchers chose a NaP/biscodyl composition for comparison, which gave far better results. The Examiner cites Afridi and his colleagues as searching for alternative methods which are rapidly acting and require less fluid intake and are easier to tolerate. Rather than teach Applicant's invention, this points out the unobviousness of it: Applicant was addressing the same problems with PEG-ELS that Afridi did; Afridi *et al.*, however, do not formulate a NaP/PEG electrolyte-less combination, but select a NaP/biscodyl composition for their research. If Applicant's compositions are as clearly obvious as contended by the Examiner, why did Afridi *et al.* not choose these for their research? For that matter, if Applicant's compositions are as obvious as the Examiner claims, why have they not been in use for years instead of the problematic products?

Matsuoka *et al.* disclose a PEG/ELS composition with NaP. Matsuoka also acknowledge that the salty taste of the composition is attributable to the electrolytes in the PEG composition; however, these highly skilled researchers never think to remove them from the solution, presumably because of the concern about consequential electrolyte balance.


The remaining references (Wood *et al.*, Vining, Robb-Nicholson, and Christine *et al.*) describe the subject-matter of claims herein dependent upon the independent claims for their patentability. Applicant does not claim to have invented the use

of clear liquid diets, flavorings, or packets with bowel cleansing compositions and none of the references cited combine these optional ingredients or packaging means with compositions of the inventions.

Reconsideration and withdrawal of this rejection is accordingly respectfully requested.

Applicant also submits herewith a sworn affidavit with Exhibits A-E attesting to the characteristics and utility of the present inventions. The Examiner is particularly directed to page 6, paragraph 15 of the affidavit which offers expert testimony as to the disclosure of WO 98/43654 as it pertains to ^{the instant} ~~advancing~~ ^{application} ~~gastrological knowledge.~~

Respectfully submitted,


 Jean A. Buttmi
 Reg. No. 24,236

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Hoffman, Wasson & Gitler, P.C.
 2461 South Clark Street
 Suite 522
 Arlington, Virginia 22202
 703.415.0100
 Customer No. 20741

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